DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MDSGBN

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-53

April 15, 1999

James S. Wadsworth, President
Sherwood Technologies
1403 Wren Court
Longwood, Florida 32750

Dear Mr. Wadsworth:

We are writing to you because on March 2, 1999, FDA Investigator Ronald T. Weber, collected information that revealed serious regulatory problems involving intracranial electrodes, Class II, which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS/GMP REGULATIONS

1) Failure to establish and maintain a quality system appropriate for the medical device designed and manufactured, e.g., no written quality assurance procedures exist for this device. [21 CFR 820.5]

2) Failure to establish and maintain record keeping procedures, e.g., there are no device master (DMR) or device history records (DHR) for this device. [21 CFR 820.820.181 & 184].

3) Failure to establish and maintain finished test records documenting finished device acceptance to ensure each production run or lot of device meets acceptance criteria. [21 CFR 820.80(d)].

4) Failure to establish and maintain all required procedures and records required by the QS/GMP regulation [21 CFR 820.20(e)]

The inspection also determined that your device is misbranded within the meaning of section 502(o) in that a notice or other information respecting the device was not provided as required by such section or section 510(k). You failed to respond to the Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE) request dated May 28, 1998 for additional information concerning your 510(k) premarket notification.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We believe 180 days to make the necessary corrections is excessive and that it should take no longer than 30 days to effect corrective action. Please justify in your response why this much time is necessary to take appropriate corrective action.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Any further distribution of an unapproved device is on your own responsibility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District